

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. Box 1347
WILMINGTON, DELAWARE 19899-1347

302 658 9200
302 658 3989 FAX

JACK B. BLUMENFELD
302 351 9291
302 425 3012 FAX
jblumenfeld@mnat.com

August 4, 2008

VIA E-FILING

The Honorable Sue L. Robinson
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 North King Street
Wilmington, Delaware 19801

Re: *Siemens Medical Solutions USA, Inc. v. Saint-Gobain
Ceramics & Plastics, Inc.*; C.A. No. 07-190 (SLR)

Dear Judge Robinson:

I write in response to Saint-Gobain's July 28th letter to the Court, which attempted to address the Court's questions at the July 18th hearing regarding whether Dr. McClellan should be precluded from testifying on three "studies" and related "test data" that were never disclosed in discovery and that are alleged by Saint-Gobain to be unknown and unavailable to Siemens, this Court, and even Saint-Gobain counsel itself. Specifically, Saint-Gobain sought additional time to respond to concerns over:

- 1) Whether by claiming the underlying information was secret, Saint-Gobain was using the studies both "as a sword and a shield" by relying on the alleged "result" of the studies without ever revealing the study itself; (Tr. at 79-80);
- 2) How the Court or Siemens could ever verify that Dr. McClellan's recollection of the data was reliable without access to the underlying data; (Tr. at 75-78); and
- 3) Whether there is any caselaw suggesting that expert testimony based on undisclosed data can satisfy the "sufficient facts and data" requirement of Rule 702. (Tr. at 79-81).

At the hearing, Saint-Gobain counsel admitted that he was not aware of any federal court decision allowing the type of unverifiable expert testimony at issue here. Saint-Gobain asked the Court for additional time to try to find caselaw supporting the sort of testimony Dr. McClellan seeks to offer and was given a week to try to do so. One week later, however, nothing changed. Saint-Gobain provided, by its own admission, "no directly controlling authority" to support its position. Saint-Gobain's week of fruitless searching confirms what Siemens argued in its briefing and at the hearing: *there is no support for the type of unverifiable expert testimony*

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Saint-Gobain seeks to offer because allowing it would turn the Federal Rules on their head and be a return to pre-*Daubert*, anything-goes, expert testimony.

Despite the lack of support for its position, Saint-Gobain nevertheless suggests that a few cases salvage Dr. McClellan's proposed testimony. None of those cases, however, deals with the issue at hand. As discussed below, they either support *Siemens'* position or have little relevance to the decision before the Court. And while a review of Saint-Gobain's cases confirms that Siemens' motion should be granted, an additional point deserves mention here.

Nowhere in Saint-Gobain's submission does it mention Federal Rule of Evidence 702, the very source of concern with Dr. McClellan's proposed testimony. Nor does Saint-Gobain ever discuss or analyze the Supreme Court's *Daubert* decision describing the Court's gatekeeper function and how the undisclosed information is exactly the material necessary for the Court to perform that function. Because Rule 702, *Daubert* and its progeny strongly support Siemens' motion and the Court's concerns, a brief discussion on that issue is provided below. Saint-Gobain's lack of citation to or even discussion of Rule 702 ignores the root cause of its extra submission in the first place. Rule 702, amended to reflect the shift away from unreliable "expert" opinions and to codify the Court's gatekeeper function, specifically limits expert testimony in such a way as to exclude the three "secret" studies that Dr. McClellan tries to offer in his report. Rule 702 requires that three prerequisites be met before accepting such testimony:

(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

There is no way that Saint-Gobain's attempt to offer only the outcome (and Dr. McClellan's 5-year-old memory of it at that) of test data related to three "secret" studies can satisfy these requirements. "Sufficient facts or data" are required, yet here *we have no facts* and no data. "Reliable principles and methods" are required, yet here *we know nothing* about the principles and methods used. Saint-Gobain has never explained how the Court can perform its Rule 702 gatekeeping function without any of this information because it is impossible to do so.

Similarly, Saint-Gobain's statement that its research failed to disclose "directly controlling authority" ignores that the Supreme Court's own words in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) provide exactly the authority forbidding such testimony. Any proposed expert testimony "must be supported by appropriate validation — *i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. To determine if the appropriate validation is present, a trial court must conduct "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." *Id.* at 592-93. When expert testimony purports to be scientific in nature, "*evidentiary reliability* will be based upon *scientific validity*." *Id.* at 590 n.9 (emphasis in original). This inquiry into evidentiary reliability by the Court should not look to the results of the expert's opinion, but instead be "focus[ed] ... solely on principles and methodology" underlying the study. *Id.* at 595.

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Despite these clear dictates, Saint-Gobain continues to ask this Court to accept Dr. McClellan's testimony and turn a blind eye to the absence of *any* scientific validation for these opinions, in essence, by substituting Dr. McClellan's own assurances of both his memory's accuracy and the test's underlying validity in the first place. As Judge Kozinski noted when addressing *Daubert* on remand, when a court is "presented with only the experts' qualifications, their conclusions and their assurances of reliability ... *that's not enough.*" *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (emphasis added).

Several courts since *Daubert* have also excluded testimony with flaws similar to Dr. McClellan's. Shortly after the Supreme Court's decision, the Third Circuit interpreted *Daubert* to require the following:

Daubert's requirement that the expert testify to scientific knowledge — conclusions supported by good grounds for each step in the analysis — means that *any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.*

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994) (emphasis in original); *see also Izumi Prods. Co. v. Koninklijke Philips Elecs. N.V.*, 315 F. Supp. 2d 589, 600 (D. Del. 2004) (Robinson, C.J.) ("An expert's opinion is reliable if it is 'based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his or her belief.'") (quoting *Paoli*, 35 F.3d at 742) *aff'd* 140 Fed. Appx. 236 (Fed. Cir. 2005).

When both the underlying facts — as well as the methodology applied to those facts — is kept from the Court, it is impossible to conduct any inquiry into the methodology or the presence of "good grounds" because the Court is deprived of the very information needed for that inquiry. Because proposed expert testimony can be excluded where it lacks a sufficient factual basis, an opinion that entirely fails to disclose the facts or data on which it relies could never pass the requirements of either Fed. R. Evid. 702 or *Daubert*.

Where courts have been asked to "take our expert's word for it," as Saint-Gobain does here, they have routinely rejected such suggestions and precluded the testimony. *See, e.g., Vigil v. Michelin N. Am., Inc.*, Case No. 05-001-KC, 2007 WL 2778233, at *11 & *11 n.7 (W.D. Tex. Aug. 23, 2007) (striking expert opinion whose underlying data could not be verified, therefore "opposing counsel would 'have to take [expert's] word for it'" (citation omitted); *In re Jacoby Airplane Crash Litig.*, Case No. 99-6073, 2007 WL 5037683, at *23 (D.N.J. Aug. 27, 2007) (precluding expert testimony based on personal experience without analysis or details of factual underpinning); *LinkCo., Inc., v. Fujitsu Ltd.*, No. 00 Civ. 7242(SAS), 2002 WL 1585551, at *4 (S.D.N.Y. July 16, 2002) ("A court cannot permit experts to 'offer credentials rather than analysis'" (citation omitted). To allow otherwise would allow exactly the sort of "sword/shield" problem faced here — an expert offering opinions to support a party's case without exposing that

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opinion to scrutiny under either the Court's gatekeeping function or thorough cross-examination by the other side.

The authority cited by Saint-Gobain – including its lead case that was decided more than a decade *before Daubert* and under a different version of Rule 702 – changes none of the above.

- Saint-Gobain's reliance on the *Bastanipour* case – decided *eleven years prior* to the Supreme Court's decision in *Daubert* and *almost twenty years before* enactment of the current Fed. R. Evid. 702 – demonstrates the difficulty Saint-Gobain faced in trying to find support for its position on Dr. McClellan's testimony. Worse still, the facts of this case are nothing like those in *Bastanipour*. In *Bastanipour*, the defendant was offered the opportunity to test the actual substance at issue, but declined to do any tests of its own. Moreover, some information regarding the government's tests that the expert was relying on was also made available to the defendant. *United States v. Bastanipour*, 697 F.2d 170, 177 n.2 (7th Cir. 1982). Here, Siemens does not have the opportunity to perform the same tests as those at Los Alamos, and the Los Alamos studies and data relied upon by Dr. McClellan were never made available to Siemens.
- The *Bowen* case need not be distinguished, because it supports exclusion of Dr. McClellan's testimony. Finding an expert's amended opinion to be unreliable "*ipse dixit*" because it had "not been validated by any scientific discipline, study, or entity," the *Bowen* court noted that – like here – the unsupported testimony was only offered after the expert's initial opinion was rendered unhelpful and was an unreliable "product of the instant litigation." *Bowen v. E.I. DuPont de Nemours & Co.*, No. 97C-06-194 (CHT), 2005 Del. Super. LEXIS 239, at *40-41 (Del. Super. Ct. June 23, 2005).¹ So too here Dr. McClellan's first opinion (in connection with the preliminary injunction motion) was found by the Court to be "not helpful," and the relevance of these three "secret" studies was only included in his second expert report. (D.I. 79 at 10.)
- *Forest Labs* speaks to the uncontroversial issue that an expert is not ordinarily allowed to testify about opinions that were not disclosed in his expert report. The issue here, however, is not that McClellan has failed to disclose his ultimate opinions, but that he has failed to disclose the facts and data supporting those opinions. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, 237 F.R.D. 106, 110-11 (D. Del. 2006).
- *Inline Connection Corporation* involves a motion to exclude an expert's opinion because *after analyzing* the underlying data, the defendant argued it was unreliable – a far cry

¹ *Bowen* was not decided pursuant to the Federal Rules of Evidence, but instead under the Delaware Rules of Evidence.

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from this case where Siemens has been denied the opportunity to make any such inquiry. *See Inline Connection Corp. v. AOL Time Warner Inc.*, 472 F. Supp. 2d 604, 612-13 (D. Del. 2007). Notably, Magistrate Judge Thyng permitted the expert to testify in *Inline* **because** his opinion was **not** based “on unverified sources.” *Id.* at 613. Here all we have are “unverified sources.”

- Similarly, the *Williams* court emphasized that the court’s inquiry under *Daubert* is to ensure an expert’s opinion is “based on ‘good grounds’ or methods and procedures of science.” *United States v. Williams*, 235 Fed. Appx. 925, 928 (3d Cir. 2007) (citation omitted). If Siemens and the Court are denied access to the methods used to reach these opinions, this inquiry cannot occur and, thus, the testimony should not be allowed.

Saint-Gobain’s proposed solution of a *voir dire* of Dr. McClellan would also be ineffective, if not entirely pointless. As the Court noted at oral argument, permitting Dr. McClellan to testify without requiring him to produce the information he considered would require the Court to make a finding that the **data and methodology** on which he relied is reliable solely if the Court found Dr. McClellan **himself** reliable. This is not how the Federal Rules of Evidence and the Federal Rules of Civil Procedure are designed to work together – only when the information in Fed. R. Civ. P. 26 is disclosed can the Court conduct the *Daubert* inquiry. The “*voir dire*” solution proposed by Saint-Gobain serves only to delay the decision, it does not and cannot resolve the *Daubert* problem. Something more is needed – because “**the expert’s bald assurance of validity is not enough.**” *Daubert*, 43 F.3d at 1316 (emphasis added). Dr. McClellan’s bald assertions regarding these studies and data, despite Saint-Gobain’s assurances that they are “reliable inasmuch as [they] are based on his work experience at LANL,” are no different than the excluded testimony in *Daubert* and *Vigil*. The same result is proper here – if the expert does not or cannot disclose the basis for his testimony, the testimony cannot come in. The Federal Rules – both of evidence as well as civil procedure – demand nothing less.

For these reasons, as well as those outlined in Siemens’ briefing on this motion and expressed in oral argument, Siemens respectfully requests this Court grant its motion to preclude Dr. McClellan from testifying at trial regarding studies on which he has provided no underlying facts or data – specifically the DARHT project, the GNEP program, and long-dwell-time applications identified in his expert report.

Respectfully,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

cc: Clerk of the Court (by hand and e-mail)
 Kelly E. Farnan, Esquire (by hand and e-mail)
 Frederick L. Whitmer, Esquire (by e-mail)